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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,394	05/16/2001	Naoto Miwa	SCH 1799	2377

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/787,394

Applicant(s)

MIWA ET AL.

Examiner

Shahnam Sharareh

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 29,31,32 and 35-48 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 29, 31-32, 35-48 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. Amendment filed on February 09, 2005 has been entered. Claims 29, 31-32, 35-48 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of applicant's arguments. All other arguments are addressed below.

#### ***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 29, 31-32, 35-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohno et al US Patent 4,839,265 in view Licha et al US Patent 6,258,340 (Licha I) and Licha et al US Patent 6,083,485 (Licha II) and Randall US Patent 6,114,350.

4. Applicant's arguments with respect to this rejection have been fully considered but are not found persuasive.

5. In response to applicant's argument that Ohno is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Ohno is directed to cyanine dyes. Accordingly, Ohno's compounds can be employed for any utility that a cyanine dye may have. Since the state of art showed similar type of cyanine compounds, such as those disclosed in Licha and Randall, can be used for diagnostic use, there is no reason to exclude Ohno's compound from such use. Further,

Applicant has not provided any evidence that sets forth Ohno's compounds not to be useful for diagnostic purposes.

6. Applicant then asserts that the instant case is governed by *In re Baird*, 20 US PQ2d 1550 (Fed. Cir. 1994), because the prior art teaches a vast number of compounds which cannot render the instant claims obvious. (Arguments at page 3).

In response Examiner states that contrary to Applicant's arguments the instant case has nothing to do with the scenario in the case of *In re Baird* and thus is not controlled by it. The court's holding in *Baird* was based on the close analysis of the number of the species encompassed by the genus in question. The genus in *Baird* "encompassed estimated 100 million different species." Moreover, the court reasoned that the primary reference in *Baird* indeed appeared to teach away from the selection of the rejected species, because it focused on specific species as "preferred, optimum and typical." *Id.* at 1552. Thus, the court considering the totality of the teachings in the primary reference in *Baird*, concluded that the primary reference did not teach or fairly suggest the selection of the rejected species from a big genus. *Id.* at 1552.

Unlike in *Baird*, the instant rejection employs only one compound that is disclosed by Ohno, the sodium salt of formula (I-7). All secondary art are used to show the state of art about using cyanine dyes for diagnostic purposes and *in vivo* administration. Accordingly, it was concluded that one of ordinary skill in the art at the time of invention would have been motivated to also use Ohno's compound for diagnostic purposes.

As previously stated, Licha I discloses cyanine dye compositions for diagnostic use comprising same elements as the subgenus of the claim 29 (formula III-I). Licha's formula overlap in scope with those of Ohno and the instant claims. Licha further disclose methods of using indole compounds for in vivo diagnostic procedures of identifying tumors, internal blood flow and angiography by administering to a patient indole compounds as set forth in his claim 1-4 (col 1, line 53-col 2, line 20; col 10, lines 30-67; col 13, lines 44-50; col 17, line 55-65; col 18, lines 30-65). The indole compounds of Licha meet all the instant subgenus as set forth in the instant claim 29, because Licha's compounds, as shown in col 17-18, comprise all the same substituents as instantly claimed. Therefore, cyanine groups within the subgenus of instant claim 29 have been shown to be effective for in vivo imaging. Such cyanine compounds include Ohno's formulations.

Licha II and Randall are additional evidence essentially used to show the state of art at the time of invention with regards to the use of cyanine dyes in vivo. Licha I, II and Randall show the similarity between the cyanine compounds and their method of use.

Accordingly, it was concluded that it would have been obvious to one of ordinary skill in the art at the time of invention to use the compounds of Ohno for diagnostic purposes, because as by Licha I, cyanine dyes within the subgenus group of compounds instantly claimed are used for in vivo diagnosis of tumors and assessments of blood flow.

Thus, Applicant's arguments were not persuasive for the reasons of record.

***Conclusion***

**No claims are allowed. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**SREENI PADMANABHAN**  
**SUPERVISORY PATENT EXAMINER**